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RE: Supplemental Report for Douglas J. Horn and Cindy Harp-Horn v. Medical Marijuana, Dixie Elixirs and Edibles, Red Rice Holdings, LLC and Dixie Botanicals

Dear Mr. Benjamin:

As you requested, I have examined copies you provided of the following case documents that became available recently:

1. CannLabs Certificate of Analysis for CBD 500 Dew Drop (or CBD0803MIXE2), Test ID: DED10.12.12-2 (PDF Files: 02475533xA984D; 02475534xA984D; 02475536xA984D)

2. CannLabs Certificate of Analysis: for CBD1011R&D-500 mg, Test ID: DED10.12.12-5 (PDF File: 02475535xA9B4D)

3. Report of Cindy S. Orser, Ph.D. dated September 29, 2017.

As I indicated in my initial report, the Frequently Asked Questions (FAQ) page on the DixieX.com website in October 2012 included the following statements:

> *All of our products are tested multiple times during the manufacturing process using both traditional ISO17025 chemical testing facilities, as well as cannabinoid testing facilities, all of which are based in the U.S.*
>
> *We are not aware of any psychotropic effects associated with using these products. The complete product line of Dixie X is consistently tested throughout the formulation and manufacturing process to ensure it meets all local, state and Federal guidelines and laws.*

Despite the claims that these products are tested multiple times during the formulation and manufacturing process, the test results and certificates of analysis associated with the actual lot number of the product purchased by Mr. Horn are apparently not available and were not provided to Dr. Orser for her review in preparation of her report. Instead, Dr. Orser cited certificates of analysis generated by CannLabs, Inc. for two representative Dixie Elixirs and Edibles products (Dixie X Hemp CBD 500 mg Dew Drop, also identified as CBD0803MIXE2 Consumable, and CBD1011R&D-500 mg Consumable) that were manufactured and tested in the October 2012 timeframe as was the product purchased by Mr. Horn.

The certificate of analysis for the Dixie X Hemp CBD-500 mg Dew Drop (CBD0803MIXE2 Consumable) product indicated a THC content of 0.05% (500 µg/g or 500 ppm) and a cannabidiol content of 516.78 mg. The content of THC measured in this product represents an amount 2.9 times higher than the 170 µg/g THC concentration determined by EMSL Analytical, Inc. in the 100 mg product submitted by Mr. Horn.

The certificate of analysis for the CBD1011R&D-500mg Consumable product indicated a THC content of 0.04% (400 µg/g or 400 ppm) and a cannabidiol content of 263.45 mg. The content of THC measured in this product represents an amount 2.4 times higher than the 170 µg/g THC concentration determined by EMSL Analytical, Inc. in the 100 mg product submitted by Mr. Horn.

In her report, Dr. Orser stated that the analysis of these Dixie Elixir products showed "an order of magnitude less than the state and federal limit of 0.3% THC; in fact, the same Dixie X Hemp 500 mg Dew Drop contained just 0.05% THC." The certificate of analysis issued by CannLabs, Inc., for the Dixie X Hemp 500 mg Dew Drop (PDF File: 02475534xA984D) also lists the maximum legal limit for THC at 0.3%.

CannLabs, Inc. ceased business operations in Colorado in November 2015 and the ability to access documentation associated with these, or other, analyses may not be feasible.

Dr. Orser asserted in her report that EMSL Analytical, Inc. does not appear to have "any accreditation to test cannabis, and therefore no accredited validated procedures." She apparently reached this conclusion by reviewing information contained on the EMSL website, and without knowledge of the specific test procedures and reference materials used by EMSL to conduct this analysis.

In her report, Dr. Orser opined that the "plaintiffs should have been aware that the labeling of the Dixie X Hemp 500 mg Dew Drop product was not definitive of product content" and that the "primary responsibility in a largely unregulated industry in 2012 rests on the buyer/consumer."

Supplemental Opinions

My review and analysis of the additional records in this case, lead me to conclude the following within a reasonable degree of scientific certainty:

1. The results provided in the certificates of analysis as representative of the 500 mg Dixie X Elixir product originally purchased and consumed by Mr. Horn confirm that the product contains a measurable amount of THC. Since a measurable quantity of 500 µg/g (500 ppm) THC was present in a Dixie X Elixir containing 516 mg CBD, the product would be classified as a Schedule 1 controlled substance as defined under 21 U.S.C. §1308.11.

2. The state and federal limit of 0.3% THC content that Dr. Orser cites in her report to justify statutory compliance of the Dixie X Elixir is only applicable to the cultivation, importation and industrial use of hemp material[1, 2]. The 0.3% limit does not apply to final product formulations in which the presence of any amount of THC would render it a Schedule 1 controlled substance as described under 21 U.S.C. §1308.11. Although Dixie X Elixir is a product made from cannabis plant material (hemp) that contains tetrahydrocannabinols, it would be ineligible for an exemption to a Schedule I classification under 21 U.S.C. §1308.35 since it is manufactured and intended for human consumption.

3. The presence of at least 500 ppm of THC measured in the representative Dixie X Elixir product containing nominally 500 mg CBD is 10-fold higher than the 50 ppm THC concentration in the hemp products that were used in studies[3-9] that demonstrated the ability of those products to produce positive THC drug screen results. Since there has been no additional evidence to indicate that Mr. Horn had a history of either recreational or medicinal marijuana use, Mr. Horn's exposure to approximately 500 ppm THC from his daily use of Dixie X Elixir for eight days preceding his DOT urine sample collection on October 9, 2012 was remains the direct cause of his positive THC drug test result that subsequently led to his loss of employment.

4. Dixie X Elixir was advertised as containing "0%" THC and public statements by the company's managing director stated the product "contains no THC". Based on the Certificates of Analysis for the representative Dixie Elixir products, these claims are refuted by the measured presence of THC in the products and represent false advertisement that would be seemingly unlawful under 15 U.S.C §52.

5. Without any knowledge or review of the processes, instrumentation, reagents and method validation status EMSL Analytical, Inc. employed to test the 100 mg Dixie X Elixir product submitted for analysis by Mr. Horn, Dr. Orser has no foundation upon which to assert that the laboratory appeared to lack accreditation to test cannabis, and therefore had no accredited validated procedures.

6. Dr. Orser's opinion that the "plaintiffs should have been aware that the labeling of the Dixie X Hemp 500 mg Dew Drop product was not definitive of product content" and that the "primary responsibility in a largely unregulated industry in 2012 rests on the buyer/consumer" lacks scientific foundation and appears to be a personal viewpoint. To the contrary, since Dixie X Elixir was a Schedule I controlled drug substance under 21 U.S.C. §1308.35, it was subject to specific packaging and labelling requirements under 21 U.S.C. §1302.03. Consequently, the product label was required to have definitive information of product content. The Dixie X Elixir product label did not bear the symbol reflecting that it was a Schedule I substance nor did it list THC as an ingredient. A prospective consumer would not be able to make an informed decision about whether to use the Dixie X Elixir product or not if the product label lacked required ingredient content, the label lacked the required symbol reflecting that it was a Schedule I controlled substance and advertising and public statements asserting the product contained no THC were false and misleading.

If you need additional explanation of the concepts involved or have further need of my services, please contact me.

Very truly yours,

Kenneth D. Graham, Ph.D., R.Ph.

References

1. Bosca, I and Karus, M. The Cultivation of Hemp: Botany, Varieties, Cultivation and Harvesting. Hemptech, Sebastopol, CA (March 1998), pp. 59-61.
2. Health Canada Schedule 1089: Industrial Hemp Regulations (SOR/98-156), Amendment of the Schedule to the Narcotic Control Regulations (SOR/98-158), Ottawa, ON, Canada, http://www.hc-sc.gc.ca/hpb-dgps/therapeut/, April, 1998.
3. Fortner, N, Fogerson, R, Lindman, D, Iverson, T and Armbruster, D. Marijuana-positive urine test results from consumption of hemp seeds in food products. J. Anal. Toxicol. 1997;21:476-481.
4. Bosy, TZ, Cole, KA. Consumption and quantitation of Δ^9-tetrahydrocannabinol in commercially available hemp seed oils and products. J. Anal. Toxicol. 2000;24:562-566.
5. Lehmann, T, Sager, F, Brenneisen, R. Excretion of cannabinoids in urine after ingestion of cannabis seed oil. J. Anal. Toxicol. 1997;21:373-375.
6. Callaway, JC, Weeks, RA, Raymon, LP, Walls, HC, Hearn, WL. A positive THC urinalysis from hemp (cannabis) seed oil. J. Anal. Toxicol. 1997;21:319-320.
7. Alt, A and Reinhardt, G. Positive cannabis results in urine and blood samples after ingestion of hemp food products. J. Anal. Toxicol. 1998;22:80-81.
8. Costantino, A, Schwartz, RH, Kaplan, P. Hemp oil ingestion causes positive urine tests for Δ^9-tetrahydrocannabinol carboxylic acid. J. Anal. Toxicol. 1997;21:482-485.
9. Struempler, RE, Nelson, G and Urry, FM. A positive cannabinoids workplace drug test following the ingestion of commercially available hemp seed oil. J. Anal. Toxicol. 1997;21:283-285.